UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEBELA INTERNATIONAL LIMITED, *et al.*, Plaintiffs, vs. ACTAVIS LABORATORIES FL, INC., *et al.*, Defendants.	Civil Action No.: 17-4789-CCC-MF **OPINION**
SEBELA INTERNATIONAL LIMITED, *et al.*, Plaintiffs, vs. PRINSTON PHARMACEUTICAL INC., *et al.*, Defendants.	Civil Action No.: 17-4964-CCC-MF

CECCHI, District Judge.

Currently pending before the Court are the joint motions of Plaintiffs Sebela International Limited, Sebela Ireland Limited, and Sebela Pharmaceuticals Inc. (collectively, "Sebela") seeking preliminary injunctions barring Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (collectively, "Actavis") and Prinston Pharmaceutical, Inc., Solco Healthcare U.S., LLC, and Huahai U.S. Inc. (collectively, "Prinston") (together with Actavis, "Defendants") from launching generic versions of Sebela's Brisdelle® drug product on the basis that such products would infringe the claims of

U.S. Patent No. 9,393,237 (the "'237 patent").[1] For the reasons set forth below, the Court denies Sebela's motions.

I. BACKGROUND

A. The Prior Litigation

The '237 patent is related to two other patents that have been the subject of litigation before this Court: U.S. Patent Nos. 8,658,663 (the "'663 patent") and 8,946,251 (the "'251 patent"). All three patents relate generally to methods of using paroxetine to treat thermoregulatory dysfunction. With the exception of certain language in the claims, the specification of the '237 patent is identical to those of the '663 and '251 patents.

The '663 and '251 patents are the subject of an ongoing consolidated litigation between Sebela and Defendants. *In re Sebela Patent Litig.*, No. 14-6414 (D.N.J.) (the "Prior Litigation"). The Prior Litigation stemmed from Defendants' filings of Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval to market generic versions of Sebela's paroxetine mesylate product sold under the name Brisdelle® (Defendants' "ANDA Products"). The Court conducted a bench trial in the Prior Litigation from December 8, 2016 to December 14, 2016. The parties submitted post-trial briefing and proposed findings of fact and conclusions of law. Closing arguments were held on February 24, 2017 and March 13, 2017. Subsequently, on June 9, 2017, the Court issued an Opinion and Order, (No. 14-6414, ECF Nos. 273 & 274), holding that the claims of the '663 and '251 patents were invalid as obvious.[2] The Court further noted that based

[1] Sebela's motions as filed also sought temporary restraining orders ("TROs"). Following a conference call with the Court, Defendants agreed not to launch their generic products until at least September 1, 2017, obviating the need for TROs. In a subsequent letter to the Court, Defendants agreed not to launch until the issuance of this Court's decision or September 15, 2017, whichever comes first.

[2] Defendants stipulated to infringement of certain claims of the '663 and '251 patents in the Prior Litigation. No. 14-6414, ECF No. 175 at 2-3. Two additional patents, U.S. Patent Nos. 5,874,447

on the evidence presented at trial, if the Court had found the patents' claims nonobvious, it would have concluded that they were invalid for lack of credible utility and lack of written description. No. 14-6414, ECF No. 273 at 60-65.

B. The '237 Patent

The '237 patent issued on July 12, 2016 from U.S. Application No. 14/577,227. On or about October 20, 2016, before trial in the Prior Litigation, Actavis notified Sebela that its ANDA contained a Paragraph IV certification[3] alleging that the claims of the '237 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Actavis's ANDA Product. ECF No. 8-6.[4] On or about December 20, 2016, following trial, but prior to closing arguments, Prinston notified Sebela that its ANDA contained a Paragraph IV certification alleging that the claims of the '237 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Prinston's ANDA Product. ECF No. 8-7.

On June 28, 2017, following the Court's June 9, 2017 Opinion and Order holding that the '663 and '251 patent claims are invalid as obvious, Sebela filed Case No. 17-4789 against Actavis asserting infringement of the '237 patent claims. On June 30, 2017, the Court held a conference call with Sebela and Actavis, at which point Sebela indicated that it would file a motion for a TRO and a preliminary injunction. Subsequently, on July 6, 2017, Sebela filed Case No. 17-4964

(the "'447 patent") and 7,598,271 (the "'271 patent"), were also asserted in the Prior Litigation. Sebela agreed to withdraw the claims of the '447 patent in exchange for Defendants' agreement not to launch their ANDA Products until June 10, 2017, the expiration date of the '447 patent, (*id.* at 2), and the Court found the sole asserted claim of the '271 patent not infringed (No. 14-6414, ECF No. 273 at 26-43).

[3] Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[4] Unless otherwise indicated, ECF No. citations included in this Opinion refer to filings in Civil Action No. 17-4789.

against Prinston asserting infringement of the '237 patent claims. The following day, Sebela filed motions for a TRO and a preliminary injunction in both cases. The Court conducted a teleconference with all parties, and a briefing schedule was set. Pursuant to a stipulation by the parties, Defendants have agreed to refrain from launching their ANDA Products at this time. No. 17-4789, ECF No. 18 at 2-3; No. 17-4964, ECF No. 20 at 2-3. Following briefing, the Court held a hearing on July 28, 2017.

II. LEGAL STANDARD

Although this Court has discretion to grant preliminary injunctions under 35 U.S.C. § 283, "a preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993); *accord Vascular Sols., Inc. v. Boston Sci. Corp.*, 562 F. App'x 967 (Fed. Cir. 2014). Accordingly, the party seeking a preliminary injunction bears the burden of establishing its entitlement to such extraordinary relief. In assessing the appropriateness of such relief, the Supreme Court has set forth four factors for the Court to consider: "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *accord AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010); *Amazon.com, Inc. v. Barnesandnoble.com*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Moreover, a party seeking a preliminary injunction "must establish *both* 'likelihood of success on the merits *and* irreparable harm' for the court to grant a preliminary injunction." *The Chamberlain Grp., Inc. v. Techtronic Indus. Co. Ltd.*, 676 F. App'x 980, 984 (Fed. Cir. 2017) (quoting *Amazon.com*, 239 F.3d at 1350); *accord Altana Pharma AG v.*

Teva Pharm. USA, Inc., 532 F. Supp. 2d 666, 673 (D.N.J. 2007), *aff'd*, 566 F.3d 999 (Fed. Cir. 2009).

"To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1364 (Fed. Cir. 2017); *accord Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 (Fed. Cir. 2017); *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). As the Federal Circuit has stated, "[a] preliminary injunction should not issue if the accused infringer 'raises a substantial question concerning either infringement or validity.'" *Metalcraft of Mayville*, 848 F.3d at 1364 (quoting *Amazon.com*, 239 F.3d at 1350); *accord Tinnus Enters.*, 846 F.3d at 1202; *AstraZeneca LP*, 633 F.3d at 1050. When assessing the likelihood of success of a patent infringement claim, the Court engages in the same two-step process used in considering infringement later in the litigation, by first determining the scope and meaning of the asserted patent claims and then comparing the construed claims to the allegedly infringing product. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003).

At the preliminary injunction stage, the Court must also consider any invalidity defenses raised by the defendants. Because an issued patent carries a presumption of validity under 35 U.S.C. § 282, the accused infringer bears the burden of coming forward with evidence of invalidity, which the patentee may then rebut. *Tinnus Enters.*, 846 F.3d at 1205. However, "[t]he burden on the accused infringer to show a substantial question of invalidity at this stage is lower than what is required to prove invalidity at trial. 'Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.'" *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999,

1006 (Fed. Cir. 2009) (quoting *Amazon.com*, 239 F.3d at 1359). "The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." *Amazon.com*, 239 F.3d at 1359.

In addition to establishing likelihood of success, Sebela has the burden of showing that it will be irreparably harmed if its motion for a preliminary injunction is not granted. *See Nutrition 21 v. United States*, 930 F.2d 867, 870-71 (Fed. Cir. 1991); *Altana*, 532 F. Supp. 2d at 681. Irreparable harm must be established as a separate element, independent of any showing of likelihood of success; irreparable harm can no longer be presumed. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). "The adequacy of money damages is a factor to be considered in deciding whether or not harm is irreparable." *Graceway Pharms., LLC v. Perrigo Co.*, 722 F. Supp. 2d 566, 569 (D.N.J. 2010). The Federal Circuit has stated that "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21*, 930 F.2d at 871.

III. ANALYSIS

A. Sebela has failed to demonstrate a likelihood of success on the merits

i. Claim Construction

The parties dispute the interpretation of claim 1 of the '237 patent. Claim 1 recites:

> A method for treating a female patient suffering from thermoregulatory dysfunction associated with menopause, **consisting of** administering a dosage form of paroxetine to said patient in an amount, based on the paroxetine moiety, of 7.5 mg/day.

'237 patent 5:39-43 (emphasis added). In particular, the parties argue about the effect of the transitional phrase "consisting of"—specifically, whether that phrase serves to limit the contents of the "dosage form" or just the steps of the claimed method. Sebela argues that the use of the

phrase "consisting of" limits the claimed invention such that the claimed dosage form contains a single active pharmaceutical ingredient ("API")—paroxetine. In contrast, Defendants argue that the phrase "consisting of" merely limits the method to the single step of administering a dosage form that contains paroxetine. In other words, the dosage form may contain other APIs in addition to paroxetine.

At this stage in the litigation, the Court preliminarily adopts Sebela's proposed construction. By way of background, the Court notes "[t]he phrase 'consisting of' is a term of art in patent law signifying restriction and exclusion, while, in contrast, the term 'comprising' indicates an open-ended construction." *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000). In general, when a patent drafter uses "consisting of," the patent claim covers what follows the transitional phrase and nothing else. *Id.* at 1383. Here, the use of the transitional phrase "consisting of" appears to create a presumption that the patent claim is limited to those elements listed, namely, the "administering a dosage form of paroxetine to [a] patient in an amount . . . of 7.5 mg/day." As Defendants point out, the grammatical structure of claim 1 seems to indicate that the phrase "consisting of" relates back to the method rather than relating forward to the "dosage form," i.e., the method "consists of" the listed step. This suggests that the phrase "consisting of" serves to limit the method to the single listed step ("administering a dosage form of paroxetine to [a] patient in an amount . . . of 7.5 mg/day"). As discussed below, however, Defendants have not convinced the Court that the "dosage form" limitation in that single listed step is open, i.e., includes APIs other than those explicitly recited in the claim. Thus, even if the Court were to accept Defendants' argument that "consisting of" only limits the method, this Court preliminarily finds that claim 1 does not encompass the administration of paroxetine in conjunction with any other API.

Defendants argue that while the use of the limiting transitional phrase "consisting of" may prevent additional steps from being performed as part of the claimed method, the phrase does not "close down" the dosage form administered within one of those steps. ECF No. 19 at 20. Defendants contend that the term "dosage form of paroxetine" remains open-ended, and that the "plain meaning" of the term is "simply a dosage form that contains paroxetine." *Id.* at 21. Defendants' position is not supported by the case law that they cite. In the first case Defendants rely upon, the court had to determine the effect of "consists of" in the phrase "consists of a mixture containing." *ITP, Inc. v. BP Corp. N. Am., Inc.*, No. 03-5823, 2005 WL 3542577, at *12-13 (S.D. Tex. May 2, 2005), *report and recommendation adopted*, No. 03-5823, 2005 WL 3542575 (S.D. Tex. Dec. 27, 2005). The court concluded that despite the use of the limiting phrase "consists of," the mixture could contain elements beyond those listed after the term "containing." In doing so, however, the court considered that "mixture" and "containing" are both open-ended terms, and the court further noted that additional claim language suggested that the mixture could contain other components. *Id.*

In contrast, here, claim 1 does not recite language that opens the "dosage form of paroxetine" such that it can contain additional, unrecited APIs. In contrast with the claim at issue in *ITP*, claim 1 does not provide for a "dosage form *containing* paroxetine," but instead specifies a "dosage form *of* paroxetine." This difference is significant. While "containing" is generally considered an open term, several courts have construed "of" to be a closed or mostly closed term. *See, e.g., Teva Pharms. USA, Inc. v. Sandoz Inc.*, 810 F. Supp. 2d 578, 586 (S.D.N.Y. 2011) (construing "of" to have the same meaning as "consisting essentially of"); *StemCells, Inc. v. Neuralstem, Inc.*, No. 06-1877, 2011 WL 3565246, at *20 (D. Md. Aug. 12, 2011) (rejecting plaintiff's argument that "of" was open-ended). Similarly, while the claim at issue in *ITP* recited

other language that suggested the identified mixture could contain other components, here, Defendants have not identified any such language in claim 1.[5] Accordingly, the Court finds *ITP* distinguishable.

The second case Defendants rely upon is similarly unavailing. In *Maytag Corp. v. Electrolux Home Products, Inc.*, the court held that the open term "comprising," when used as a transitional term before a series of claimed steps, does not open up each of the claimed steps. 411 F. Supp. 2d 1008, 1072 (N.D. Iowa 2006) (concluding that the claimed method may "comprise" additional, unrecited steps besides the steps expressly claimed but "that does not mean that each step as expressly claimed is not complete in and of itself"). The Federal Circuit reached the same conclusion the next year in *Dippin' Dots, Inc. v. Mosey*, holding that "[t]he presumption raised by the term 'comprising' does not reach into each of the six steps to render every word and phrase therein open-ended." 476 F.3d 1337, 1343 (Fed. Cir. 2007). In other words, the Federal Circuit in *Dippin' Dots* (and the district court in *Maytag*) concluded that the use of an *open* transitional term could not serve to *open* the individual limitations of the claim. Defendants suggest the inverse

[5] Defendants point to the dependent claims of the '237 patent to support their position that the "dosage form of paroxetine" allows for other APIs. ECF No. 19 at 21-22. Specifically, Defendants contend that the use of the open-ended term "comprises" to describe the required dosage form in each dependent claim "strongly suggests that 'dosage form' in claim 1 is also open ended." *Id.* at 22. Because the Court "must not interpret an independent claim in a way that is inconsistent with a claim which depends from it," *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997), it is proper for the Court to consider the structure of the dependent claims of the '237 patent in ascertaining the scope of claim 1. The Court is mindful, however, that "[w]hile it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1360 (Fed. Cir. 2016) (quoting *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1577 (Fed. Cir. 1993)). The Court finds Sebela's reading of the dependent claims more persuasive—namely, that the dependent claims, which themselves do not mention any APIs other than paroxetine, merely limit the single API in the dosage form of claim 1 to a specific physical form of paroxetine or its pharmaceutically acceptable salt. *See* ECF No. 23 at 3.

is true and argue that the use of a *closed* transitional phrase cannot serve to *close* the individual limitations of the claim. But Defendants presume that those individual limitations are already open. This does not follow from the Federal Circuit's reasoning in *Dippin' Dots*, which made clear that each step in a claimed method "must . . . be practiced as recited in the claim for a process to infringe." *Id.* In other words, each step constitutes a separate limitation of the claim, and each step must be performed as written in order for the claim to be infringed. While the use of the term "comprising" allows for a finding of infringement where additional steps are also performed, the term cannot be used to change the meanings of the recited steps and thereby abrogate the clearly laid out limitations. *Id.* Here, Defendants would have the Court conclude that the individual limitation of "dosage form of paroxetine" is open where there is no open transitional term or phrase used; in fact, a *closed* transitional phrase is used. Defendants have not provided the Court with a reason for doing so. Therefore, at this stage, the Court rejects Defendants' proposed construction based on the language of claim 1.

Furthermore, additional intrinsic evidence indicates that claim 1 does not cover the administration of dosage forms containing other APIs. Specifically, the specification of the '237 patent does not discuss, or include any examples of, dosage forms containing paroxetine and one or more other APIs. In addition, the Court notes that during the prosecution of the '237 patent, then-pending claim 1 was amended to change the term "comprising" to "consisting of" to overcome a rejection over the '251 patent claims based on statutory double patenting under 35 U.S.C. § 101. This suggests that the amendment was intended to narrow the scope of then-pending claim 1, particularly when considered in light of statements in the specification of the '237 patent that distinguish prior art, in part, on the basis that the prior art teaches combination therapies. *See* '237 patent 2:28-42.

Additionally, the Court notes that at this stage it does not conclude that claim 1 excludes dosage forms that include non-active ingredients, or excipients. *See Warner Chilcott Co., LLC v. Zydus Pharms. (USA) Inc.*, No. 11-1105, 2013 WL 1729383, at *5 (D. Del. Apr. 22, 2013) ("A person skilled in the art would not read the patent to exclude the basic excipients disclosed in the patent, as they are naturally associated with pharmaceutical formulations."); *cf. Teva Pharms.*, 810 F. Supp. 2d at 586 (construing "of" to have the same meaning as "consisting essentially of").

Accordingly, at this stage in the litigation, the Court concludes that claim 1 of the '237 patent does not encompass the administration of paroxetine in conjunction with any other API.

ii. Defendants' non-infringement position

Based on the Court's claim construction, the Court concludes that Sebela has demonstrated that it would likely be able to establish infringement. Representative claim 1 of the '237 patent is very similar to claim 1 of the '251 patent. Claim 1 of the '251 patent recites:

> A method for treating a patient suffering from a thermoregulatory dysfunction associated with menopause, **comprising** administering a dosage form of paroxetine to said patient in an amount, based on the paroxetine moiety, of 7.5 mg/day.

'251 patent 6:14-18 (emphasis added). The only differences between the two claims are the insertion of the word "female" in the '237 patent and the use of the transitional phrase "consisting of" in the '237 patent where the '251 patent uses "comprising." Defendants have previously stipulated that the use of their ANDA Products infringes claim 1 of the '251 patent. No. 14-6414, ECF No. 175 at 3. Defendants' ANDA Products are clearly intended to treat "female patient[s]," and under the Court's claim construction, the substitution of "consisting of" for "comprising" does not alter the scope of claim 1 of the '237 patent in a manner relevant to the question of infringement by Defendants' ANDA Products.

iii. Defendants' affirmative invalidity defense

In the Prior Litigation this Court previously found that claim 1 of the '251 patent was invalid for obviousness.[6] The Court further noted that based on the evidence presented at trial, if the Court had found claim 1 of the '251 patent nonobvious, it would have concluded that claim 1 was invalid for lack of credible utility and lack of written description. No. 14-6414, ECF No. 273 at 60-65.

In concluding claim 1 of the '251 patent was invalid as obvious, the Court considered an array of prior art. In particular, it considered:

> (1) an article by V. Stearns, *et al.*, published in 2000 in the Annals of Oncology ("Stearns 2000"), which reports the results of a pilot trial assessing the efficacy of paroxetine hydrochloride in controlling hot flashes in breast cancer survivors and "strongly suggest[s]" that 20 mg/day doses of paroxetine hydrochloride was effective for treating hot flashes;
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> (2) a 2005 follow-up to Stearns 2000, which published the results of a much larger, randomized clinical trial testing the efficacy of paroxetine in treating hot flashes in the Journal of Clinical Oncology ("Stearns 2005"), and which "recommend[ed] prescribing [a] low-

[6] To prove that an asserted claim of a patent is invalid as obvious under 35 U.S.C. § 103, Defendants bear the burden of establishing by clear and convincing evidence that the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Obviousness is a question of law that is predicated on several factual inquiries. *See Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, there are four considerations: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as long-felt but unsolved need, failure of others, praise by others in the industry, and unexpected results. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). In determining what would have been obvious to a person of ordinary skill in the art, the use of hindsight is not permitted. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) (cautioning against "the distortion caused by hindsight bias" and "arguments reliant upon *ex post* reasoning"). In *KSR*, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 418.

> dose of paroxetine (10 mg) to women who desire a nonhormonal pharmacologic treatment for their hot flashes";
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> (3) an international patent application published in 2002 ("Coelingh"), which describes a method of treating hot flashes by administering a combination of a serotonin re-uptake inhibitor and vitamin B6 and disclosed ranges of paroxetine doses that encompass 7.5 mg/day; and
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> (4) a 2004 U.S. patent application ("Lemmens"), which discusses the advantages of paroxetine mesylate over paroxetine hydrochloride for pharmaceutical use, noting its better thermal stability.

Considering this prior art, and in light of its conclusion that the 7.5 mg/day value set forth in the claims was not a critical value, the Court concluded that it is "clear that all of the elements of the claims were present in the prior art, and there was a motivation to combine them." No. 14-6414, ECF No. 273 at 56, 58. The parties raise the same prior art in this case.

Given the limited nature of the two differences between claim 1 of the '251 patent and claim 1 of the '237 patent, the Court concludes that at this stage Defendants have established that there is a substantial question of invalidity of the '237 patent based on obviousness. The first difference between the two claims is the addition of the word "female" to limit the scope of the patients treated. This difference does not change the Court's obviousness analysis from the analysis the Court previously performed in the Prior Litigation. The prior art the Court previously considered explicitly dealt with the treatment of female patients. *See, e.g.*, Stearns 2000; Stearns 2005.

The second difference between the two claims is the substitution of the limiting phrase "consisting of" in the '237 patent for the open term "comprising" in the '251 patent before describing the steps of the claimed method. Sebela argues that this change in language weighs heavily against applying the Court's prior obviousness analysis because the Court's prior

obviousness conclusion was based on a claim construction that permitted the coadministration of paroxetine with another API, while claim 1 of the '237 patent does not cover coadministration. ECF No. 7 at 17-19. Specifically, Sebela suggests that adopting its claim construction would mean that Defendants "can no longer rely on Coelingh." ECF No. 23 at 5. This, however, is not the case. Although Coelingh discloses coadministration of paroxetine with a B vitamin, the question raised by Defendants is one of obviousness, not of anticipation.[7] Accordingly, Coelingh remains an instructive reference, particularly in light of Lemmens, which teaches the use of low doses of paroxetine to treat a variety of other conditions, and a 1998 article by Loprinzi, *et al.*, published in the Journal of Clinical Oncology, which discloses the treatment of hot flashes with low doses of venlafaxine, a different antidepressant. Therefore, the Coelingh reference, particularly when read in conjunction with Stearns 2000 and Stearns 2005, raises a substantial question concerning validity.

Moreover, if the Court were to accept Defendants' proposed claim construction, the Court would find that there is a substantial question concerning the validity of the '237 patent. Defendants' construction would encompass coadministration of paroxetine and another API, so the analysis would be essentially the same as the analysis performed by the Court when it found the '251 patent claims invalid. Therefore, under either proposed claim construction, the Court would find there is a substantial question concerning validity, and Sebela has not demonstrated a likelihood of success on the merits.

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[7] Although anticipation requires that every limitation be found in a single prior art reference, *see, e.g., Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010), for the purposes of obviousness, "[a] reference must be considered for everything it *teaches*" and "the combined teachings of the prior art as a whole must be considered," *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). *See also Illumina Cambridge Ltd. v. Intelligent Bio-Sys., Inc.*, 638 F. App'x 999, 1005 (Fed. Cir. 2016).

B. Sebela has failed to demonstrate irreparable harm

Sebela contends that the launch of Defendants' ANDA Products would "severely and irreparably harm Sebela's market position, reputation, and revenues." ECF No. 7 at 35. Specifically, Sebela argues that failure to enjoin the launch of Defendants' ANDA Products will result in lost sales revenue, irreversible price erosion, [redacted] loss of goodwill and reputation, and lost research and development opportunities. *See id.* at 38-47.

As an initial matter, this Court has recognized that "[b]oth loss of market share and price erosion are economic harms and are compensable by money damages" even in the "context of generic competition in the pharmaceutical industry." *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-1887, 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2007), *aff'd*, 280 F. App'x 996 (Fed. Cir. 2008); *see also Ortho Biotech Prods., L.P. v. Amgen Inc.*, No. 05-4850, 2006 WL 3392939, at *6 (D.N.J. Nov. 21, 2006) ("Lost revenues are a classic economic loss, and can easily be remedied by monetary damages at the end of a trial on the merits."). While Sebela contends that "it is not possible to fully quantify the resulting damages to Sebela," (ECF No. 7 at 47), "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial," *Nutrition 21*, 930 F.3d at 871. The Federal Circuit has observed that a "district court's reliance on possible market share loss would apply in every patent case where the patentee practices the invention." *Id.* Moreover, although Sebela's damages might be significant, and the "complexities and uniqueness of the pharmaceutical industry might make such calculation an arduous task," *Novartis Corp. v. Teva Pharms. USA, Inc.*, Nos. 04-4473, 06-1130, 2007 WL 1695689, at *27 (D.N.J. June 11, 2007), Sebela itself appears to support Defendants' assertion that Sebela's damages are calculable; calculable damages may be reparable by money damages. *Id.*;

ECF No. 7 at 39 [redacted]

Sebela also argues that the "lost sales of Brisdelle® and consequential loss in cash flow will also negatively impact Sebela's ability to invest in research and development of new patient treatments." ECF No. 7 at 45. The Federal Circuit has recognized, however, that "[i]f a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief." *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) (affirming the district court's finding that the movant failed to establish irreparable harm based, in part, on the loss of research opportunities). The Federal Circuit reasoned that "[s]uch a rule would convert the 'extraordinary' relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits." *Id.* Any potential damage to Sebela's ability to invest in research and development does not compel a finding of irreparable harm.

[redacted] ECF No. 7 at 40. According to Sebela, [redacted] will affect sales of its other products. *Id.* These harms stem from the alleged loss in sales revenue caused by the introduction of Defendants' ANDA Products, which, as discussed above, is compensable in money damages. In addition, Sebela appears able to calculate the damages attributable to the lost sales of its other products. *See id.* at 41; ECF No. 9 ¶¶ 26, 37. Defendants also point out that Sebela had acquired Brisdelle® following the previous owner's, Noven Therapeutics LLC, [redacted] ECF No. 19 at 38. As Sebela itself acknowledges, Sebela was able

to [redacted] of Brisdelle®, (*see* 7/28 Tr. at 23:22-24:1), and Sebela has not provided enough evidence that it would be unable to [redacted]. Moreover, the Court agrees with Defendants that Sebela's complaint about the alleged harm from changed formulary status and [redacted] is "another way of saying that Sebela will make less money," which is compensable in money damages. ECF No. 19 at 36. Sebela further contends that a generic launch will impair its goodwill, reputation, and potential for future investment, which in turn will impact relationships with physicians, patients, Managed Care Organizations, and future investment partners. *See* ECF No. 7 at 45-47. This Court agrees with Defendants that these harms alleged by Sebela are speculative.

In response to Sebela's assertions that its "[redacted]" upon generic entry, (ECF No. 10 ¶ 103), Defendants contend that it is unreasonable to believe that Sebela neither anticipated nor prepared for the possibility of generic entry in as early as 2017. ECF No. 19 at 31-33. This Court agrees. Sebela purchased Brisdelle® on July 25, 2016 while the Prior Litigation was ongoing. *Id.* at 31. [redacted] Sebela has known for a year of the Prior Litigation, that the generic drug companies filed ANDAs, and that the 30-month stays of FDA approval as to Actavis and Prinston would be expiring in March and April of 2017, respectively. Moreover, Sebela was aware that Defendants' previous agreement not to launch their ANDA Products would terminate on June 10, 2017. *Id.* at 34; No. 14-6414, ECF No. 171 at 3. This Court finds it "difficult to accept" that Sebela "does not have a business plan in place to deal with the introduction of . . . generic version[s]" of Brisdelle®. *Altana*, 532 F. Supp. 2d at 682. [redacted]

[redacted]. It is further "unreasonable to believe" that Sebela "sought out and approved a corporate transaction that would cripple the company upon expiration" of Defendants' 30-month stays less than a year after the acquisition. *Altana*, 532 F. Supp. 2d at 683; *Altana*, 566 F.3d at 1010-11. In light of these facts, the Court finds that Sebela has overstated the impact of generic entry on Sebela's business.

In addition, the Court agrees with Defendants that Sebela's actions are "inconsistent with those of a company facing imminent and irreparable harm." ECF No. 19 at 34. Since Sebela joined the litigation in September of 2016, it has had multiple opportunities to assert the '237 patent. Instead, it appears that Sebela chose to wait for a decision on the validity of related patents in the Prior Litigation. *See* ECF No. 7 at 11 ("[U]ntil the Court found the '663 and '251 patents invalid as obvious in view of the Coelingh reference, there was no reason to burden the Court and the parties with an additional lawsuit asserting the '237 patent."). (*See also* 7/28 Tr. at 68:8-11, 70:16-17, 71:2-8.) Sebela's litigation approach belies the alleged emergent nature of the harm.

For the reasons discussed above, this Court finds that Sebela has not demonstrated that it will suffer irreparable harm if an injunction is not granted to prevent Defendants from launching their ANDA Products. Due in part to Sebela's own efforts to calculate (preliminarily) the potential monetary harm to Sebela, this Court is not persuaded that such harm is incalculable.

C. Balance of the equities and public interest

As the Court has found that Sebela has not met its burden on the first two factors, it need not articulate findings regarding the balance of the equities and the public interest. *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) ("[W]e specifically decline today to require a district court to articulate findings on the third and fourth factors when the court denies

a preliminary injunction because a party fails to establish either of the two critical factors."); *Novartis Corp.*, 2007 WL 1695689, at *3 ("[T]his Court may deny the motion without articulating findings respecting the other factors if Novartis fails to establish either of the first two factors."). However, it will nevertheless address them for the purpose of completeness. *Reebok Int'l*, 32 F.3d at 1555 ("[I]t is always preferable that a district court make findings regarding each of the four factors which weigh in the balance concerning whether to deny a preliminary injunction.").

Turning first to the balance of the equities, or hardship, the Court finds that this factor weighs in favor of Defendants. Sebela's claim of hardship seems to be a mere restatement of its case of irreparable harm, which has been discussed above. Moreover, Sebela's apparent strategic decision not to raise the '237 patent as an issue in the Prior Litigation is what has created the urgency in this matter and Sebela's claimed need for an injunction in the first place. At the same time, granting the preliminary injunctions would cause Defendants to lose profits they might have earned on sales of their ANDA Products during this injunction period, essentially rewarding Sebela for its decision not to raise this issue earlier. *See* ECF No. 19 at 41; ECF No. 19-1 ¶ 56.

The Court finds that the public interest is neutral. The very structure of the Hatch-Waxman Act recognizes the competing public interests of protecting valid patent rights and increasing competition in the pharmaceutical industry by facilitating the approval of generic versions of drugs. *See Graceway Pharms.*, 722 F. Supp. 2d at 580; *CollaGenex Pharms., Inc. v. IVAX Corp.*, 375 F. Supp. 2d 120, 140-41 (E.D.N.Y. 2005). Both interests are at stake in this case. Beyond noting these broad competing interests, neither side has presented compelling reasons for why the balance should be tipped in this case. (*See* 7/28 Tr. at 24:10-11.)

IV. CONCLUSION

Because Sebela has failed to establish its entitlement to the relief requested, the Court finds that a preliminary injunction should not issue.[8]

An appropriate Order accompanies this Opinion.

Dated: September 14, 2017

HON. CLAIRE C. CECCHI
United States District Judge

[8] In its reply papers, Sebela raised an alternative request for a Rule 62(c) injunction pending appeal if the Court denies the instant preliminary injunction motions, which was discussed at the July 28th hearing. (7/28 Tr. at 7:12-15, 21:21-23:7.) Although this issue does not seem to have been raised in Sebela's moving papers, the Court will nevertheless consider it briefly. The Supreme Court has provided four factors "regulating the issuance of a stay" under Rule 62(c): (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *see Citizens for Rational Coastal Dev. v. U.S. Fed. Highway Admin.*, No. 07-4551, 2008 WL 2774529, at *3 (D.N.J. July 16, 2008) (noting that a party requesting a Rule 62(c) stay "bear[s] a very heavy burden of persuasion") (citation omitted). For the reasons set forth above, the Court concludes that Sebela has not made a strong showing that it is likely to succeed on the merits, Sebela will not be irreparably injured absent a stay, and although the public interest is neutral, Sebela has not shown that the issuance of a stay will not substantially injure Defendants. Accordingly, the Court concludes that Sebela has failed to meet its burden.